## Children's Health Protection Advisory Committee

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April 8, 2003

Honorable Christine Todd Whitman Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Ave, NW Washington D.C. 20460

Dear Administrator Whitman:

The Children's Health Protection Advisory Committee (CHPAC) is concerned about the potential public health impacts of environmental contaminants in human milk, and our current inability to evaluate these risks adequately. Very limited data are available to assess the presence of environmental chemicals in human milk and to evaluate associated risks. This complex issue deserves more attention from EPA and would benefit from additional data collection. Because human milk is the preferred primary source of infant nutrition and has well documented benefits compared with formula feeding, our goal should be to ensure we understand and reduce any risks associated with environmental contaminants in human milk.

EPA, in partnership with other Federal agencies, should work toward standardizing human milk sampling and analysis and towards consistently and comprehensively incorporating exposure through human milk consumption into risk assessment. Results of these efforts, in conjunction with a human milk monitoring program, could inform risk management decisions at EPA as well as at other Federal agencies. A more comprehensive description of human milk contamination with environmental chemicals is attached.

The EPA co-sponsored a conference "Chemical Contaminants in Breast Milk" in 2001, and a workshop titled "Technical Workshop on Human Milk Surveillance and Research on Environmental Chemicals in the United States," in February 2002. The conference focused on defining the issues with chemical contaminants in human milk, and the symposium focused on methods for obtaining human milk samples, analyzing those samples for environmental contaminants, and interpreting the results. The results of these symposia (1,2) provide a great starting point for EPA, the Center for Disease Control (CDC) and other Federal agencies to address potential public health impacts from exposure to environmental contaminants in human milk.

CHPAC makes the following recommendations to EPA:

1. Develop standardized methods for human milk sampling and analysis and establish a human milk monitoring program in partnership with other Federal agencies. Although collection of human milk is noninvasive and fairly simple, sample handling and analysis is complex. The Technical Workshop pointed to the need for standardized methods for collection and analysis to compare data across populations and laboratories.

A human milk-monitoring program would help define the extent of human milk contamination in the U.S., identify common environmental contaminants in human milk, and characterize typical concentrations to which infants are exposed. In addition, data from human milk monitoring would provide information on body burdens of some contaminants (for example, persistent organic pollutants) in breast-feeding women, and identify trends in contaminant concentrations. Such trends can demonstrate the efficacy, or lack thereof, of regulatory action.

- 2. Incorporate the human milk exposure pathway into risk assessment. Currently, the human milk exposure pathway is evaluated only for some lipophilic compounds, mainly dioxins, in some instances (for example, a dioxin-contaminated site). Further, the models available to estimate risk focus only on highly lipophilic compounds and do not address other contaminants of concern. Human milk is often the only dietary source of exposure to chemicals during the first few months of life. We recommend that EPA expand their human milk risk assessment methods to include non-lipophilic chemicals. In addition, we recommend that EPA require consideration of this exposure in all risk assessments. The EPA should use information from human milk monitoring to expand and validate risk assessment models.
- 3. Coincident with the monitoring initiative, EPA should provide a proactive health education campaign about the purpose of monitoring in the context of the benefits of breast-feeding. New mothers need to make appropriate decisions about feeding their babies. This involves weighing the benefits and risks of formula and breast feeding and putting any risks into perspective. The EPA, in conjunction with appropriate federal agencies and other interested parties, needs to communicate the many health benefits of breast-feeding so the documented presence of contaminants, or even the existence of human milk monitoring, does not unduly discourage breast-feeding.

Once national monitoring data become available and risk assessment models that comprehensively assess human milk contaminants are developed, the EPA and other agencies will need to take further steps to adequately protect infants and children. EPA and other agencies together should:

- Conduct research to assess the health impacts of contaminants found in human milk
- Identify high exposure populations and populations exposed to unusual contaminants via human milk.

April 8, 2003 Page 3

> Base risk management and risk mitigation decisions on data from human milk monitoring and surveillance, as well as on risk assessments that more fully characterize risk from contaminants in human milk.

The CHPAC appreciates the difficulties and complexities in evaluating health impacts from exposure to environmental chemicals through human milk. We support breast-feeding as the optimum course for new mothers and infants and in no way want to discourage the practice. Quite the contrary, breast-feeding should be encouraged. However, we also see a strong need to evaluate the extent of contamination of human milk, assess potential health impacts, and reduce risks associated with environmental contaminants in human milk.

CHPAC would be happy to discuss the issue with EPA and help in any way we can to foster the suggestions we make above.

Sincerely,

Melanie A. Marty, Ph.D., Chair

Children's Health Protection Advisory Committee

- Cc: L. Blackburn, Associate Director, Office of Children's Health Protection,
  Office of the Administrator
  - J. Rodman, Associate Director, Office of Children's Health Protection,
    Office of the Administrator
  - P. Gilman, Assistant Administrator, Office of Research and Development

<sup>(1)</sup> Chemical Contaminants in Breast Milk, Mini-Monograph, P.J. Landrigan, editor; In: Environmental Health Perspectives 110(6), June 2002.

<sup>(2)</sup> Technical Workshop on Human Milk Surveillance and Research on Environmental Chemicals in the United States. J.S. LaKind, editor; In: Journal of Toxicology and Environmental Health. Part A: Current Issues 65(22), November 2002

## Attachment Contaminants in Human Milk

Human milk is the optimal food for infants. Many studies have demonstrated the positive health benefits of breast-feeding on growth and development including increased resistance to both acute disease (i.e., infections) and chronic disease (i.e., asthma, allergies, diabetes). Thus, breast-feeding is recommended by the American Academy of Pediatrics (AAP, 1997) the World Health Organization (WHO, 2001), the U.S. Department of Health and Human Services (DHHS, 2000), and the U.S. Food and Drug Administration (USDA, 1998).

Many studies have been published in the scientific literature demonstrating the presence of environmental contaminants in human milk (cited in Solomon and Weiss, 2002; Landrigan et al., 2002). Most of these studies have focused on persistent organic pollutants (POP) because of their propensity to bioaccumulate, such as DDT, polychlorinated dibenzodioxins and furans, and PCBs (Jensen, 1987). Other studies have looked at the content of heavy metals such as lead, mercury, and cadmium in human milk (Grandjean et al., 1995; Abadin et al., 1997; Gundacker et al., 2002; Oskarsson et al., 1996; Drexler and Schaller, 1998). Some studies have demonstrated that human milk is a major pathway of exposure to these persistent environmental contaminants including PCBs and PBBs (Kuwabara et al., 1978; Niessen et al., 1984; Jacobson et al., 1989) and dioxins (Smith et al, 1987; Patandin et al, 1997, 1999). Recently, scientists have focused on an emerging class of environmental contaminants found in increasing levels in human fat and milk, the brominated flame retardants polybrominated biphenyl ethers (PBDEs) (Hooper and McDonald, 2000). Studies in Europe have demonstrated increasing concentrations of these compounds in human milk over time (Noren and Mieronyte, 1998, 2000), and studies in California found increased levels in marine life and human fat (She et al., 2002). These contaminants are typical of POPs in that their fat solubility results in bioaccumulation up the food chain. Infants who breast-feed can get a significant fraction of their total lifetime intake of these POPs in their first year of life (Patandin et al, 1999; Smith, 1987). Many chemicals can get into human milk besides the POPs. Caffeine, alcohol and other drugs, pesticides and other industrial and household chemicals can enter human milk (Findlay 1983; Pellizzari et al., 1982; Schreiber, 1997). Other properties of compounds that influence the entry into human milk include ionizability and propensity for protein binding. The pH of serum and milk differ slightly; thus, the ionizability of a compound at serum and human milk pH can influence the relative concentrations of the compounds in each compartment. Blood has a larger amount of protein and thus protein binding affinity of a compound also influences access to human milk (Findlay, 1983).

To assess the risk from environmental contaminants in human milk, we must have a greater understanding of the magnitude of exposures from breast-feeding and of the toxicity of chemicals found in human milk. There are some limited efforts to address these issues going on at the Federal level. In the proposed National Children's Study, there are discussions about analyzing human milk for some environmental contaminants as a marker of exposure. The EPA's Endocrine Disruptor Screening and Testing Committee recommended that EPA prioritize pesticides, industrial chemicals and other environmental

April 8, 2003 Page 5

chemicals for human milk analysis (EDSTAC, 1998). The National Institutes of Health (NIH) has granted limited funding to university researchers to study contaminants in human milk.

Data from human milk monitoring would provide information on trends in contaminant concentrations. Such trends can demonstrate the efficacy (or lack thereof) of regulatory action. For example, in Sweden efforts to reduce environmental exposure to the dioxins, furans, and PBDEs led to reduced human milk concentrations (Noren and Mieronyte, 1998; Noren and Mieronyte, 2000).

## Research Needs

- Infants are still developing and are likely to be more susceptible to some
  environmental contaminants. For many contaminants, there are large data gaps
  about the impacts of these toxicants on human development. Research needs include
  toxicologic and epidemiologic studies to investigate effects of exposure at various
  developmental stages and to address various health endpoints including
  neurotoxicity, immunotoxicity, impacts on endocrine function, cancer risk.
- Not all women in the U.S. are exposed to the same levels of environmental contaminants or even to the same contaminants. There are populations that are more highly exposed or are exposed to unusual contaminants because of geography, lifestyle, occupation, and other unique attributes. For example, the Inuit whose diet is based on seals have considerably higher concentrations of POPs in their bodies than do people who have a more typical North American diet (Muckle et al., 2001). A human milk-monitoring program will provide information on typical exposures, but may not identify populations whose exposures are unusually high or are otherwise unique. Infants in these populations may be particularly at risk for adverse health outcomes.

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April 8, 2003 Page 6

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- April 8, 2003 Page 7

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